Original Effective Date: 06/23/2023
Current Effective Date: 09/29/2024
Last P&T Approval/Version: 04/26/2023
Next Review Due By: 04/2025
Policy Number: C25282-A

Filspari (sparsentan)

PRODUCTS AFFECTED

Filspari (sparsentan)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Primary immunoglobulin A nephropathy (IgAN)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IgAN):
   1. Documented diagnosis of Primary Immunoglobulin A Nephropathy (IgAN)
      AND
   2. Documentation diagnosis was confirmed by kidney biopsy
      AND

3. Documentation that member has failed to achieve a reduction in proteinuria under 1 gram/day while receiving maximally tolerate doses of a Renin-angiotensin-system (RAS) inhibitor (ACE inhibitor or ARB) for at least 3 months
   AND
4. Documentation that member has had a trial and failure of ONE formulary preferred glucocorticoid for at least 2 months
   AND
5. Documentation that member's urine protein-to-creatinine ratio [UPCR] ≥1.5 (consistent with FDA-approved labeling) and eGFR ≥30 mL/min/1.73 m2
   NOTE: UPCR ≥ 1.5 indicates a risk of rapid progression
   AND
6. Prescriber attests to or clinical reviewer has found member is not currently receiving dialysis or has not undergone kidney transplant.
   AND
7. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Filspari (sparsentan) include: Pregnancy, concurrent use with angiotensin receptor blockers, endothelin receptor antagonists, or aliskiren]
   AND
8. Prescriber attests a recent review of member's current medication has been completed and there is no concomitant use of Strong CYP3A inducers (i.e., rifampin), acid reducing agents (i.e., histamine H2 receptor antagonist and PPI proton pump inhibitor), strong CYP3A inhibitors (i.e., itraconazole), angiotensin receptor blockers, endothelin receptor antagonists, aliskiren or Sensitive P-gp and BCRP substrates

CONTINUATION OF THERAPY:

A. PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IgAN):

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms
   AND
4. Prescriber attests a recent review of member's current medication has been completed and there is no concomitant use of Strong CYP3A inducers (i.e., rifampin), acid reducing agents (i.e., histamine H2 receptor antagonist and PPI proton pump inhibitor), strong CYP3A inhibitors (i.e., itraconazole), angiotensin receptor blockers, endothelin receptor antagonists, aliskiren or Sensitive P-gp and BCRP substrates

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified nephrologist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

Maximum allowable 400mg once daily

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
IgAN Agents - Endothelin & Angiotensin II Receptor Antag

FDA-APPROVED USES:
Indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g
This indication is approved under accelerated approval based on reduction of proteinuria. It has not been established whether Filspari slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Per the KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases, kidney biopsy is the “gold standard” for diagnostic evaluation of glomerular disease. The guideline further notes that IgAN can only be diagnosed with a kidney biopsy (Chapter 2, reference 3). Additionally, the use of an ACE inhibitor or ARB up to a maximally tolerated or allowed dose is considered first line therapy for the treatment of hypertension and proteinuria. The guideline defines a high risk for progressive disease as proteinuria greater than 0.75 to 1 gram despite the use of optimized supportive care, including an ACE inhibitor or ARB, for at least 90 days. For those patients who remain at high risk of progressive CKD despite the maximized supportive care, immunosuppressive drugs should be considered.

Filspari REMS
For all patients, FILSPARI is available only through a restricted program under a REMS called the FILSPARI REMS because of the risk of hepatotoxicity and embryo-fetal toxicity. Important requirements of the FILSPARI REMS include the following:
• Prescribers must be certified with the FILSPARI REMS by enrolling and completing training.
• All patients must enroll in the FILSPARI REMS prior to initiating treatment and comply with monitoring requirements.
• Pharmacies that dispense FILSPARI must be certified with the FILSPARI REMS and must dispense only to patients who are authorized to receive FILSPARI.
Further information is available at www.filsparirems.com or 1-833-513-1325.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Filspari (sparsentan) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Filspari (sparsentan) include: Pregnancy, concurrent use with angiotensin receptor blockers, endothelin receptor antagonists, or aliskiren. Avoid concomitant use of strong CYP3A inhibitors, strong CYP3A inducers, acid reducing agents, and sensitive P-gp and BCRP substrates.

OTHER SPECIAL CONSIDERATIONS:

Filspari (sparsentan) has a black box warning for hepatotoxicity and embryo-fetal toxicity.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

Filspari TABS 200MG
Filspari TABS 400MG

REFERENCES

1. Filspari (sparsentan) [prescribing information]. San Diego, CA: Travere Therapeutics, Inc; February 2023.
2. Fellström, B. C., Barratt, J., Cook, H., Coppo, R., Feehally, J., de Fijter, J. W., Floege, J., Hetzel, G., Jardine, A. G., Locatelli, F., Maes, B. D., Mercer, A., Ortiz, F., Praga, M., Sørensen, S. S., Tesar, V., Del Vecchio, L., & NEFIGAN Trial Investigators (2017). Targeted-release budesonide versus placebo in patients with IgA nephropathy (NEFIGAN): a double-blind, randomised, placebo-controlled phase 2b trial. Lancet (London, England), 389(10084), 2117–2127. https://doi.org/10.1016/S0140-6736(17)30550-0
3. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. Kidney Int. 2021;100(4S):S1–S276.
4. Lv, J., Wong, M. G., Hladunewich, M. A., Jha, V., Hooi, L. S., Monaghan, H., Zhao, M., Barbour, S., Jardine, M. J., Reich, H. N., Cattran, D., Glassock, R., Levin, A., Wheeler, D. C., Woodward, M., Billot, L., Stepien, S., Rogers, K., Chan, T. M., Liu, Z. H., … TESTING Study Group (2022). Effect of Oral Methylprednisolone on Decline in Kidney Function or Kidney Failure in Patients With IgA Nephropathy: The TESTING Randomized Clinical Trial. JAMA, 327(19), 1888–1898. https://doi.org/10.1001/jama.2022.5368

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval	Q3 2024
NEW CREATION	Q2 2023